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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,903	11/21/2003	Ulrike Schmid	059490-5025	7366
9629	7590	09/07/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				COE, SUSAN D
ART UNIT		PAPER NUMBER		
1655				

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/717,903	SCHMID ET AL.
	<b>Examiner</b> Susan D. Coe	<b>Art Unit</b> 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 June 2005.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12, 15 and 16 is/are rejected.
- 7) Claim(s) 13 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed June 28, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claim 14 has been cancelled.
3. Claims 15-16 have been added.
4. Claims 1-13 and 15-16 are pending.

#### ***Claim Rejections - 35 USC § 112***

5. Claims 1-9, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the specification is enabled for prevention of diarrhea in weaning mammals. However, as discussed in the previous Office action, in order to be enabled for prevention of an ailment, the specification must show that the ailment can be prevented in each and every instance of that ailment. Applicant's specification does not set forth any evidence that the claimed method is able to prevent diarrhea for all potential causes of diarrhea. For example, known causes of diarrhea include bacterial infection, viral infection, food intolerance, parasites, reactions of medicines, and functional bowel disorders (see <http://digestive.niddk.nih.gov/ddiseases/pubs/diarrhea/> - page 2). Applicant's specification only shows a link between the claimed composition and treating diarrhea caused by bacterial infection. Applicant does not show that the composition is able to prevent diarrhea. Thus, a person of ordinary skill in the art would be forced to experiment unduly in order to

determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of diarrhea.

6. Claims 1, 3-9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because it is not clear what ages are encompassed by the limitation of "young." Thus, the metes and bounds of the claims are unclear.

***Claim Rejections - 35 USC § 102***

7. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,149,961 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claimed food composition is not taught by the reference because the reference does not teach using the food as an anti-diarrhea composition. However, this is considered a recitation of the intended use. The recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant also argues that the reference does not teach using the composition as an animal feed and that this difference results in structural differences between the two. However, claims must be given their broadest reasonable interpretation. Humans are animals; thus,

“animal feed” also encompasses food specifically manufactured for humans. Thus, even if there is a structurally difference between the food of the reference and a food intended for a non-human mammal, the claim is still considered to anticipate the stated claims.

***Allowable Subject Matter***

8. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. Claims 1-9, 15, and 16 would be allowable if they are drawn solely to treating diarrhea rather than preventing diarrhea and if they are amended to overcome the 112 2<sup>nd</sup> rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

*Susan D. Coe*

*8-30-05*

Susan D. Coe  
Primary Examiner  
Art Unit 1655